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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,243	09/26/2001	Curt R. Eyster	LIFE063	8576

7590 12/26/2007
LifeScan, Inc.
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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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12/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/963,243	Applicant(s) EYSTER ET AL.	
	Examiner Lyle A. Alexander	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,5-7 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirayaja et al.

Hirayaja et al teach a test device and use with a colorimeter to make optical determinations from a color liquid such as blood. Figure 1 teaches a first surface(1) and an opposite surface(5) having an aperture(51) in surface(5) that receives the sample. In columns 5-6 lines 60 – 16 respectively teach the surface(5) can be black in color having a reflectance of 5.3% at a wavelength of 640 nm. The Office has read the claimed top layer on surface(1), the bottom layer on surface(5). Hirayaja et al. teach a sample size of 20 microliters.

Hirayaja et al. do not teach the reagent pad directly contacting the sample-receiving aperture. Rather, Hirayaja et al. provides a chamber(53) between the sample receiving aperture and the reagent pad. Hirayaja et al. is also silent to the claimed sample volume of “less than or equal to 5 microliter”.

The Office is interpreting the chamber(53) taught by Hirayaja et al. as an element of the device. The court decided that the omission of an element and retention of its function is indicia of unobviousness. (see “MPEP 2144 II B” that summaries the decision In re Edge, 359 F.2d 896, 149 USPQ 556 (CCPA 1966)). Additionally, it is desirable to

eliminate an element of a device, such as a chamber(53), to reduce the cost of producing the device.

It would have been within the skill of the art to modify Hirayaja et al. and eliminate chamber(53) placing the reagent pad in direct communication with the sample receiving aperture in view of Edge above and to gain the above advantages.

With respect to the claimed volume of the sample, the court decided In re Yount (80 USPQ 141) that the size of an article under consideration is not ordinarily a matter of invention. In this case the size of the device dictates the volume of sample that would be required (e.g. a larger device would require a larger sample, etc.). Further, it is desirable in the field of analytical testing to use the minimal volume of sample to minimize the amount of sample needed. Smaller sample can be obtained in a more comfortable manner by finger prick as opposed vein puncture. Also the smaller sample obtained by finger prick do not need specialized technicians and can be done by the patient.

It would have been within the skill of the art to further modify Hirayaja et al. to require a smaller volume of blood, such as 5 microliter, to gain the above advantages of using a smaller sample in light of the teaching of Yount that size is not ordinarily a matter of invention.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirayaja et al in view of Phillips et al. (USP 5,843,692).

See Hirayaja et al. supra.

Hirayaja et al. is silent to the claimed use of a 5 microliter sample volume and a "notch" in the test strip.

Phillips et al. teach a test strip and spectrometer for the measurement of analytes in blood in the range of 635-700nm. In column 8 lines 5+ teach a preferred method of sample acquisition is by finger prick that results in a sample of 5-10 microliters of blood. Further in column 11 lines 9+ teach the test strip is optimally guided into the spectrophotometer by using a notch(15). The notch is advantageous because the slide will consistently arrive at the same location to assure high reproducibility of test results. The notch is further advantageous because the user can not place the wrong end into the spectrometer and obtain a spurious result.

The court decided In re Yount (80 USPQ 141) that the size of an article under consideration is not ordinarily a matter of invention. In this case the size of the device dictates the volume of sample that would be required (e.g. a larger device would require a larger sample, etc.). It is desirable in the field of analytical testing to use the minimal volume of sample to minimize the amount of sample needed. Smaller sample can be obtained in a more comfortable manner by finger prick as opposed vein puncture. Phillips et al. teach it is preferred to use a finger prick to obtain the sample in the volume range of 5-10 microliters.

It would have been within the skill of the art to modify Hirayaja et al. in view of Phillips et al. incorporate a notch and use a finger prick to collect a minimal blood volume of 5 microliters to gain the above advantages.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. alone or further in view of Hirayaja et al.

See Phillips et al. and Hirayaja et al. supra.

These Phillips et al. teach a reflectivity of from 0 to 100% and is silent to the specific reflectivity of less than 12%.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. Phillips et al. teach reflectivity in the range of 0 to 100% and all of the taught range is a result effective variable because it is contemplated by the reference.

It would have been within the skill of the art to modify Phillips et al. and select a reflectivity range of less than about 12 % as optimization of a result effective variable.

Hirayaja et al. teaches in column 4 lines 64-67 that black is a preferred color because it absorbs light over a broad range of wavelengths and can be applied to simultaneous measurements of a plurality of items. Columns 5-6 lines 60 – 16 respectively teach the surface(5) a black surface will have a reflectance of 5.3% at a wavelength of 640 nm which reads on the claimed reflectivity of less than about 12% at wavelengths 600-730 nm .

It would have been within the skill of the art to modify Phillips et al. in view of Hirayaja et al. and use a black surface to gain the above advantages.

Response to Arguments

Applicant's arguments filed 10/16/07 have been fully considered but they are not persuasive.

Applicant states Hirayama and Phillips fail to teach the claimed reflectance value or light frequency range. Hirayama teach in columns 5-6 lines 60 – 16 respectively teach the surface(5) can be black in color having a reflectance of 5.3% at a wavelength of 640 nm which is indistinguishable from the instant claims.

Phillips et al. teach a reflectivity of from 0 to 100% and is silent to the specific reflectivity of less than 12%. Phillips et al. teach reflectivity in the range of 0 to 100% and the selection of a reflectance of less than 12% would have been a result effective variable. The Office maintains Phillips et al. have been properly read on the instant claims.

Hirayama et al. teaches in column 4 lines 64-67 that black is a preferred color because it absorbs light over a broad range of wavelengths and can be applied to simultaneous measurements of a plurality of items. Columns 5-6 lines 60 – 16 respectively teach the surface(5) a black surface will have a reflectance of 5.3% at a wavelength of 640 nm which reads on the claimed reflectivity of less than about 12% at wavelengths 600-730 nm .

Applicant state the proposed modification of Hirayama would not achieve the claimed results. The instant claims are directed to an apparatus and in the absence of a showing otherwise, one having ordinary skill in the art would have expected to the modified apparatus to perform as described in the above rejections.

Applicant states the selection of the reflectance value is not a "result effective variable" as proposed by the Office. The Office maintains it is well known in the art to select a material based upon its reflective properties for the particular reagent system and analyte of interest. A showing the claimed reflectivity of less than 12 percent produces unexpected results in a timely, convincing and proper 1.132 Declaration that is commensurate in scope with the pending claims may be probative to refute this rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Application/Control Number:
09/963,243
Art Unit: 1797

Page 8

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander
Primary Examiner
Art Unit 1743

